K130328

JUN 0 5 2013

Section 5 - 510(k) Summary

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Date Prepared	7 February 2013
Contact Person	Sue Cho
Contact Details	Address: 15 Maurice Paykel Place, East Tamaki PO Box 14 348, Panmure Auckland, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0148
Trade Name	F&P Simplus™ Full Face Mask
Common Name	Full Face Mask
Classification Name	Non continuous ventilator IPPB (21 CFR § 868.5905, product code BZD)
Predicate Devices	K040506 Flexifit™ Series HC431 Full Face Mask, Fisher & Paykel Healthcare – for performance K121597 Eson Nasal Mask, Fisher & Paykel Healthcare – for material biocompatibility

5.1 Device Description

The F&P Simplus™ Full Face Mask is a non-invasive patient interface. The mask includes a silicone seal which covers the nose and mouth of a patient and is held in place by adjustable headgear straps. The mask connects to a single breathing tube via a swivel adaptor to receive pressurized gases. The gases delivered to the patient may be humidified and/or oxygen enriched. The exhaust holes on the mask housing allow exhaled air to be flushed out while the system is in operation.

An oxygen pressure port accessory is available to be used with the device for oxygen therapy and/or gas monitoring.

5.2 Intended Use

The F&P Simplus™ Full Face Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The F&P Simplus™ Full Face Mask is intended for Single Patient Adult Use in the home and Multiple Patient Adult Use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

5.3 Technological Characteristics Comparison

The F&P Simplus™ Full Face Mask has the following similarities to the previously cleared Fisher & Paykel Healthcare Flexifit™ Series HC431 Full Face Mask:

- Similar intended use.
- Both masks deliver CPAP gases through the nose and mouth.

The key differences between the two masks are that the F&P Simplus™ Full Face Mask:

- Has a permanently attached ball elbow rather than a detachable swivel elbow.
- Is smaller in size with under lip design as opposed to the under chin design.
- Has a modified non-rebreathing valve design.
- Has a modified headgear clip design.
- Has a modified design and location of exhaust holes.

5.4 Non-Clinical Tests

Testing of the F&P Simplus™ Full Face Mask was compared to the predicate K040506 Flexifit™ Series HC431 Full Face Mask for performance and K121597 Eson Nasal Mask for biocompatibility. These tests demonstrate substantial equivalence of the F&P Simplus™ Full Face Mask to the two aforementioned predicate masks. Copies of test reports are included in Appendix A.

The F&P Simplus™ Full Face Mask has been tested to the following standards:

- ISO 17510-2:2007 Sleep Apnea Breathing Therapy – Part 2: Masks and Applications Accessories
- ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process

5.5 Conclusion

The comparison of features, performance, and intended use demonstrate that the F&P Simplus™ Full Face Mask is substantially equivalent to the predicate K040506 Flexifit Series HC431 Full Face Mask for performance and K121597 Eson Nasal Mask for biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2013

Fisher & Paykel Healthcare, Limited
Ms. Sue Cho
15 Maurice Paykel Place, East Tamaki
P.O. Box 14 348, Panmure
Auckland, New Zealand 2013

Re: K130328
Trade/Device Name: F&P Simplus™ Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 6, 2013
Received: March 7, 2013

Dear Ms. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

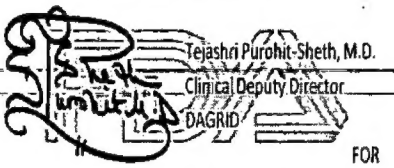
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number: K130328

Device Name: F&P Simplus™ Full Face Mask

Indications for Use:

The F&P Simplus™ Full Face Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The F&P Simplus™ Full Face Mask is intended for Single Patient Adult Use in the home and Multiple Patient Adult Use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry

Digitally signed by Anya C. Harry
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.06.04 15:25:20 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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